

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

AMGEN INC.,

Plaintiff,

v.

ACCORD HEALTHCARE, INC.,

Defendant.

C.A. No. 18-956-MSG

**DEFENDANT ACCORD HEALTHCARE, INC.'S
OPENING CLAIM CONSTRUCTION BRIEF**

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Dated: June 28, 2019

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I. INTRODUCTION

Amgen filed the Complaint in this case exactly one year ago, on June 28, 2018, alleging that Accord's generic cinacalcet hydrochloride tablets ("Accord's ANDA product") infringe U.S. Patent No. 9,375,405 ("the '405 patent").

Since that time, Accord has contended that this case is appropriate for early summary judgment of non-infringement and that formal claim construction proceedings are unnecessary. On January 9, 2019, the Court ordered the parties to file a proposed scheduling order that included not only dates for summary judgment briefing and oral argument, but also dates for claim construction briefing and a *Markman* hearing. *See* D.I. 23, 27. Summary judgment briefing was completed on March 29, 2019. *See* D.I. 29-32, 41-44, 49-52.

The claim construction positions now taken by Amgen prove Accord's point that claim construction is unnecessary in this case. First, Amgen argues *again* that the Court should reverse its previous construction of the binder limitation. Second, Amgen argues for a construction of "hydroxypropyl methylcellulose" that, even if adopted, would not affect the outcome of the case. *See* D.I. 66.

II. DISPUTED CLAIM TERMS

- A. **"from about 1% to about 5% by weight of at least one binder selected from the group consisting of povidone, hydroxypropyl methylcellulose, hydroxypropyl cellulose, sodium carboxymethylcellulose, and mixtures thereof"**

For at least the fourth time, Amgen argues to this Court that the binder limitation should be construed such that a formulation containing an unlisted binder would literally infringe the claims of the '405 patent. The Court first rejected Amgen's argument in its Memorandum and Order of February 27, 2018 in the prior litigation involving the '405 patent. *See Amgen Inc. v. Amneal Pharms. LLC et al.*, No. 16-853-MSG (D. Del.), D.I. 300, 301. The Court rejected the

argument a second time in the same case in its Memorandum and Order of April 19, 2018, in which the Court denied Amgen's Motion for Reargument of the Court's first Order. *See id.*, D.I. 357, 358. The Court rejected the argument a third time in its Trial Opinion of July 26, 2018. *See id.*, D.I. 375 at 10-11.

Collateral estoppel compels the Court to reject Amgen's fourth attempt here. "The principle of collateral estoppel, also called issue preclusion, protects a defendant from the burden of litigating an issue that has been fully and fairly tried in a prior action and decided against the plaintiff." *Comair Rotron Inc. v. Nippon Densan Corp.*, 49 F.3d 1535, 1537 (Fed. Cir. 1995).

For issue preclusion to apply, the following requirements must be met:

The defendant must show that in the prior action the party against whom estoppel is sought had a full and fair opportunity to litigate the issue; the issue was actually litigated; the controlling facts and applicable legal rules were the same in both actions; resolution of the particular issue was essential to the final judgment in the first action; and the identical issue was decided in the first action.

Id. (citing *Montana v. United States*, 440 U.S. 147, 153-55 (1979)). Amgen cannot seriously dispute that each of those requirements has been met.

The Court should therefore construe the binder limitation exactly as it has previously: to exclude from the scope of the claims any cinacalcet formulation containing an unlisted binder.

B. "hydroxypropyl methylcellulose"

Amgen invites the Court to construe "hydroxypropyl methylcellulose" to mean "any hydroxypropyl methylcellulose that is present in the composition." The reason Amgen urges such a construction is unclear. Regardless, there does not appear to be any basis for construing the term to mean anything other than simply "hydroxypropyl methylcellulose." There is no ambiguity about how the term is used in the specification or prosecution history of the '405 patent, and no indication that a person of ordinary skill would understand the term to mean anything other than "hydroxypropyl methylcellulose."

III. CONCLUSION

For the foregoing reasons, Accord respectfully requests that the Court adopt Accord's proposed claim constructions.

Respectfully submitted,

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